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RESEARCH ARTICLE

# Rising Drug Costs Drives the Growth of Pharmacy Benefit Managers Exclusion Lists: Are Exclusion Decisions Value-Based?

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**Objective.** We examine whether drugs' excluded versus recommended status on pharmacy benefit manager exclusion lists corresponds to evidence from cost-effectiveness analyses, lack of evidence, or rebates.

**Data Sources.** To find cost-effectiveness data for drugs on 2016 exclusion lists of CVS Caremark and Express Scripts, we searched the Tufts Cost-Effectiveness Analysis Registry and the peer-reviewed literature.

**Study Design.** For each excluded and recommended drug, we compared the mean cost-per-QALY, and we calculated the difference between the numbers of excluded and recommended drugs for which we could find no cost-effectiveness evidence.

**Data Collection.** As keywords in our searches, we used the brand and generic drug name and "cost-effectiveness" and "cost-per-quality-adjusted life-year." Of 240 retrieved studies, 110 were selected for analysis.

**Principal Findings.** The mean cost-per-QALY for excluded drugs was higher (\$51,611) than the cost-per-QALY for recommended drugs (\$49,474), but not statistically significant. We could find no cost-effectiveness evidence in the Registry or peer-reviewed literature for 23 of the excluded drugs, and no evidence for 5 of the recommended drugs.

**Conclusions.** Cost-effectiveness does not correlate with a drug's excluded or recommended status. Lack of cost-effectiveness evidence favors a drug's excluded status.

**Key Words.** Pharmacy benefit manager exclusion lists, reimbursement, cost-effectiveness, cost-per-QALY, prescription drug costs, formulary management, rebates

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In 2013 and 2014, the U.S. annual growth rate in prescription drug costs rose to over 10 percent (IMS Institute 2015). This was due in part to the approval of new treatments for hepatitis C and other specialty drugs. While drug spending growth in 2015 decreased to 8.5 percent, rising expenditures concern private and public payers, as well as policy makers generally (Office of the

Assistant Secretary of Planning and Evaluation, 2016). Traditionally, payers have opted to manage spending through the use of formulary management tools, such as prior authorization, cost-share tiering, step therapy, quantity limits, and indication restrictions. The use of formulary cost-share tiering has gone hand in hand with rebates. Rebates are paid to pharmacy benefit managers (PBMs) and payers in exchange for moving market share of a particular drug by way of a better formulary positioning, that is, lowering of patient cost-sharing (Cohen 2000). A portion of rebates is passed on to employers and health plans that contract with PBMs. However, it is not known how much of the rebates are passed on.

Recently, a tool has been added to the cost containment arsenal as the two largest PBMs in the United States—CVS Caremark and Express Scripts—have adopted so-called exclusion lists to tame increasing drug costs. Exclusion lists consist of a number of drugs excluded from coverage juxtaposed with recommended drugs in the same therapeutic class. The implication of a drug having excluded status is that patients must pay its full cost. PBMs assert that safety and effectiveness are the primary considerations when deciding which drugs to exclude or recommend, followed by cost (Schaeffer and McCallister 2014). As such, exclusion lists would purportedly reflect the value-based factors of clinical and cost-effectiveness. Pharmacy benefit managers establish clinical equivalency of drugs in a therapeutic classification system in terms of safety and effectiveness. Subsequently, PBMs assess the costs of therapeutic alternatives (McCallister 2013).

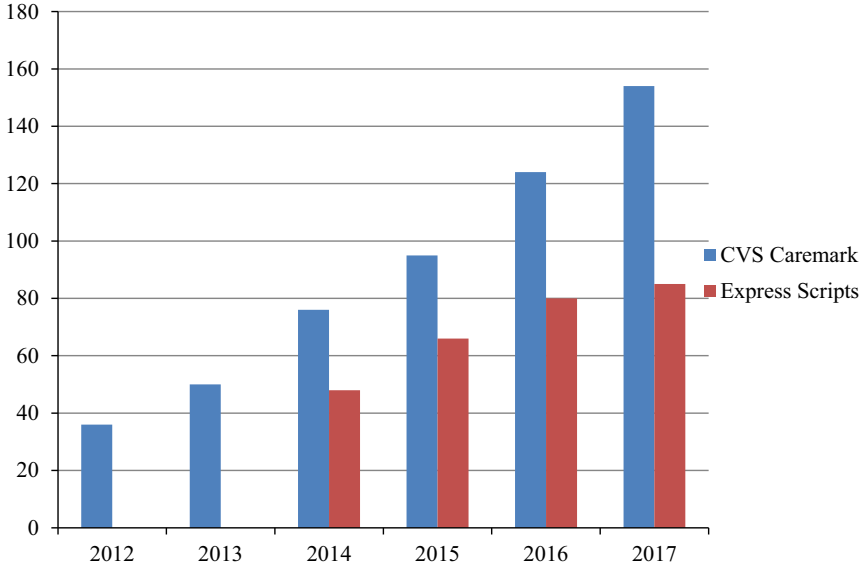
Figure 1 shows that CVS Caremark and Express Scripts, which manage the pharmacy benefits of over 150 million covered lives, have significantly enlarged their exclusion lists in recent years (Fein 2015). In 2016, Express Scripts placed 87 products on its exclusion list, while CVS Caremark put 124 drugs on its exclusion list. This represents a 65 percent increase since 2014. The lists for 2017 indicate CVS has increased the number of excluded products to 154, while Express Scripts have increased its number to 85 (Toich 2017).

Pharmacy benefit managers assert that they are implementing exclusion lists as a way to contain drug costs and counter the increase in the number of brand-name (single source) drugs in the United States with coupon or

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Figure 1: Number of Products on Exclusion Lists for the Two Largest Pharmacy Benefit Managers in the United States [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]



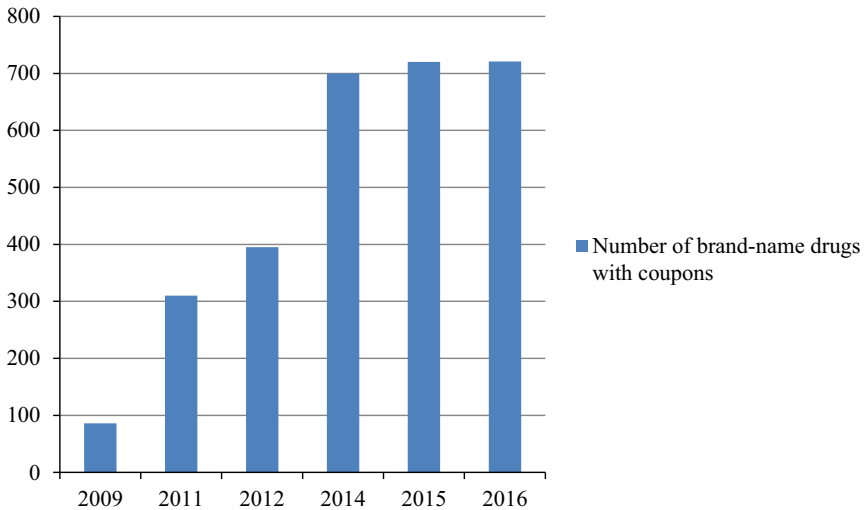
co-payment offset provisions offered to patients by drug manufacturers. Coupons reduce patient out-of-pocket expenses (co-payments). Figure 2 depicts an eightfold jump between 2009 and 2016 of the numbers of drugs with discount coupons offered to patients. Pharmacy benefit managers maintain that coupon programs serve to negate the impact of traditional formulary management tools, such as tiered patient cost-sharing (Kaitin 2016). Indeed, drug makers spent \$7 billion on co-pay assistance programs in 2015, up to 30 percent from 2014 (Congressional Research Service 2015).

Our study aims to examine possible factors underlying decisions to exclude or recommend drugs on exclusion lists operated by the two largest PBMs in the United States. Specifically, we analyze whether excluded versus recommended status is based on evidence from cost-effectiveness analyses, lack of evidence, or, by inference, rebates.

## METHODS

Given that PBMs do not disclose explicit reasoning for their exclusion decisions, we chose a method by which we can infer the role that various

Figure 2: Number of Brand-Name Drugs with Discount Coupons Offered to Patients [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]



considerations played, including cost-effectiveness. To find cost-effectiveness data for all drugs on 2016 PBM exclusion lists, we searched the Cost-Effectiveness Analysis Registry—created and maintained by the Center for the Evaluation of Value and Risk in Health at the Tufts Medical Center—as well as the peer-reviewed literature. The Tufts Registry is a comprehensive database of thousands of cost-effectiveness analyses on a wide variety of diseases and treatments. Articles containing cost-effectiveness analyses are screened and reviewed before being included in the Registry. Articles are excluded if they are reviews, editorials, or methodological pieces.

As keywords in our searches of the Tufts Registry and PubMed, we used the brand and generic drug name as well as “cost-effectiveness” and “cost-per-QALY.” We retrieved 240 peer-reviewed articles from both the Tufts Registry and PubMed literature search. Of the 240 studies we reviewed, we selected 110 to include in the analysis. Our selection criteria were as follows: All studies had to have been conducted in the past 10 years in industrialized nations and include head-to-head or standard-of-care comparisons. Seventy articles included one or more recommended drugs. And 40 articles included one or more excluded drugs. The data include cost-per-QALY estimates per drug (average cost-per-QALY when more than one study was found). In most cases, cost reported in the studies was the average wholesale price (a list price) or

international equivalent per patient or treatment cycle. The data collected included head-to-head cost-effectiveness data of branded products in the same therapeutic class and cost-effectiveness data compared to the standard of care. We eliminated cases in which the generic version of the drug was the only drug recommended and the brand-name drug the only one excluded. We also excluded non-cost-per-QALY data from our final analysis including but not limited to the “cost per life year gained,” “cost per avoided hospitalization,” and “cost per target reached.” For international studies, we converted currencies to U.S. dollars using the exchange rate as of January 15, 2017. We performed statistical tests to compare the mean cost-per-QALY of excluded and recommended drugs for both PBMs, as well as the difference between the numbers of excluded and recommended drugs for which we could find no cost-effectiveness evidence. Finally, from our data analysis, we inferred the relative importance of rebates, cost-effectiveness, and lack of evidence as determinants of exclusion and recommended status on exclusion lists (see Appendix SA2).

## RESULTS

The mean cost-per-QALY for excluded drugs was slightly higher (\$51,611) than the cost-per-QALY for recommended drugs (\$49,474). The difference, however, is not statistically significant. For excluded drugs, we observed a range of estimates from \$2,129 to \$57,763. And, for recommended drugs, we observed a range of estimates from \$2,767 to \$622,980. We removed outliers from the analysis. Given the significant variance in terms of cost-per-QALY estimates, we calculated the median cost-per-QALY for excluded drugs (\$26,240) and recommended drugs (\$25,640). The difference between median values for excluded and recommended drugs was smaller than the difference between mean values.

On Express Scripts’ exclusion list, we found no cost-effectiveness evidence for 19 excluded drugs and no cost-effectiveness data for one recommended drug. On CVS Caremark’s exclusion list, there were no cost-effectiveness data for 21 excluded drugs and no cost-effectiveness evidence for four recommended drugs. In sum, we could find no evidence for 23 excluded drugs, compared to no evidence for five recommended drugs. The difference between the numbers of excluded and recommended drugs for which no evidence of cost-effectiveness could be found was statistically significant.

Figure 3: Drugs Excluded by Both Pharmacy Benefit Managers [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

Therapeutic Class	Drugs Excluded by Both PBMs	Average Cost-per-QALY*
Inflammatory Bowel Disease, Ulcerative Colitis	Asacol HD (mesalamine)	No Evidence
Blood Pressure - Angiotensin II Receptor Antagonists	Teveten HCT (eprosartanmesylate-hydrochlorothiazide), Edarbyclor (azilsartanmedoxomil/chlorthalidone)	No Evidence
Erectile Dysfunction	Levitra (vardenafil hydrochloride)	Levitra: \$2,777 per QALY
Diabetes - Insulins	Apidra (insulin glulisine)	No Evidence
Diabetes - DPP-4 Inhibitors	Nesina (alogliptin) Onglyza (saxagliptin) Kazano (alogliptin/metformin) Kombiglyze XR (saxagliptin/metformin)	Nesina: \$1,113 per QALY Onglyza: \$2,712 per QALY Kazano: \$10,939 per QALY Kombiglyze: No Evidence
Asthma - Steroid Inhalants	Alvesco (ciclesonide)	No Evidence
Asthma -Short-Acting Beta Agonists	Proventil HFA (albuterol), Xopenex HFA (levalbuterol tartrate)	No Evidence
Obesity	Qsymia (phentermine/topiramate)	Qsymia: \$57,770 per QALY
Allergies - Nasal Steroids	Beconase AQ (beclomethasone intranasal), Omnaris (ciclesonide), Veramyst (fluticasone), Zetonna (ciclesonide)	No Evidence

Notes. \* QALY = Quality-adjusted life-year, measure of clinical benefit that accounts for the quality and quantity of life lived.

For 11 of 16 drugs excluded by both PBMs, we found no cost-effectiveness evidence. Six of 7 excluded drugs had a cost-per-QALY of less than \$50,000.

Figure 3 shows that for 11 of 16 drugs excluded by both PBMs, we found no cost-effectiveness studies. In theory, not having evidence increases PBM or payer uncertainty regarding a drug's value, making it more likely that a drug will be excluded.

Six of seven excluded drugs had a cost-per-QALY of <\$50,000. Experts suggest that drugs which fall below \$50,000 per QALY are cost-effective (Neumann, Cohen, and Weinstein 2014).

Figure 4 presents our observations that 14 drugs were excluded by either CVS Caremark or Express Scripts but recommended by the other PBM. This suggests rebates played a role in determining excluded versus recommended status. For 5 of 14 drugs, we found no cost-effectiveness evidence.

Figure 4: Drugs Excluded by Either CVS Caremark or Express Scripts but Recommended by Other Pharmacy Benefit Manager [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

Therapeutic Class	Drugs Excluded by ES, Included in CVS	Average Cost-per-QALY	Drugs Excluded by CVS, Included in ES	Average Cost-per-QALY
Type 2 Diabetes	Novolog (insulin aspart), Novolin (regular Insulin)	Novolog: \$16,838 Novolin: \$13,685	Humalog (insulin lispro), Humulin (regular insulin)	Humalog: \$19,028 Humulin: \$13,685
Diabetes - GLP-1 Receptor Agonists	Victoza (liraglutide)	Victoza: \$22,640	Bydureon (exenatide extended release), Byetta (exenatide)	Bydureon, Byetta: \$15,936
Hepatitis C	None	Not Applicable (N/A)	Viekira Pak (ombitasvir/paritaprevir/ritonavir/dasabuvir)	Viekira Pak: \$2,540 per QALY
Glaucoma	Zioptan (tafluprost ophthalmic solution)	No Evidence	Lumigan (bimatoprost)	Lumigan: Cost-per-treatment success \$1,200
Asthma	FloventDiskus (fluticasone)	No Evidence	Ventolin (albuterol sulfate), Qnasi (beclomethasone dipropionate)	No Evidence
Erectile Dysfunction	None	N/A	Viagra (sildenafil)	Viagra: \$10,145 per QALY
Dermatologic Conditions	None	N/A	Carac (fluorouracil)	No Evidence

Notes. Fourteen drugs were excluded by either CVS Caremark or Express Scripts but recommended by the other PBM. For 5 of 14 excluded drugs we found no cost-effectiveness evidence.

Figure 5 reports head-to-head comparisons of excluded versus recommended drugs in the same therapeutic class. PBMs do not necessarily cover the more cost-effective brand-name drug. In 9 of 18 instances of head-to-head comparisons of excluded versus recommended drugs, the more cost-effective drug was excluded from coverage.

## DISCUSSION

Clinical and cost-effectiveness data give us a proxy of a drug's worth. It is an imperfect measure of value from a societal perspective but a tangible one. We would expect decisions to exclude or recommend drugs to correspond to clinical and cost-effectiveness evidence. Cost-effectiveness as a proxy of value does

Figure 5: Head-to-Head Comparisons of Excluded Versus Recommended Drugs in the Same Class [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

Therapeutic Class	Drug Excluded by One of the PBMs	Drug Included by Same PBM	Head-to-Head Comparison	Better Cost-per-QALY
Hepatitis C	Harvoni (ledipasvir/sofosbuvir),	Viekira Pak (ombitasvir/paritaprevir/ritonavir/dasabuvir)	Viekira Pak v. Harvoni	Viekira Pak
Kidney Disease - Phosphate Binders	Fosrenol (lanthanum carbonate)	Phoslyra (calcium acetate)	Fosrenol v. Phoslyra	Phoslyra
Diabetes - GLP-1 Receptor Agonists	Victoza (liraglutide)	Victoza (liraglutide), Bydureon (exenatide extended release), Byetta (exenatide)	Victoza v. Bydureon or Byetta	Victoza
Glaucoma	Lumigan (bimatoprost)	Xalatan (latanoprost)	Lumigan v. Xalatan	Lumigan
Irritable Bowel Disease	Amitiza (lubiprostone)	Linzess (linaclotide)	Amitiza v. Linzess	Linzess
Constipation	Relistor (methylnaltrexone bromide)	Movantik (naloxegol)	Relistor v. Movantik	Movantik
Asthma	Alvesco (ciclesonide)	PulmicortFlexhaler (budesonide)	Alvesco v. PulmicortFlexhaler	Alvesco
	Symbicort (budesonide/formoterol)	Advair (salmeterol/fluticasone)	Symbicort v. Advair	Advair
Blood Platelet Inhibitors	Plavix (clopidogrel)	Brilinta (ticagrelor)	Plavix v. Brilinta	Brilinta
Blood Pressure – Angiotensin II Receptor Antagonists	Atacand (candesartan)	Benicar (olmesartan), Avapro (irbesartan)	Atacand v. Benicar or Avapro	Atacand
Antidepressants (SNRIs)	Cymbalta (duloxetine)	Effexor (venlafaxine)	Cymbalta v. Effexor	Effexor
Antipsychotics	Abilify (aripiprazole)	Seroquel (quetiapine), Zipra (ziprasidone), Clozaril (clozapine)	Abilify v. Seroquel; or Zipra or Clozaril	Abilify
Prostate	Jalyn (dutasteride/tamsulosin)	Flomax (tamsulosin)	Jalyn v. Flomax	Jalyn
Hematological	Aranesp (darbepoetin alfa)	Procrit (epoetin alfa)	Aranesp v. Procrit	Procrit
Multiple Sclerosis	Avonex (interferon beta-1a)	Rebif (interferon beta-1a)	Avonex v. Rebif	Avonex
Auto-Immune Disorders - Tumor Necrosis Factor Antagonists	Cimzia (certolizumab)	Enbrel (etanercept)	Cimzia v. Enbrel	Enbrel
Anti-Infectives	Valtrex (valacyclovir)	Zovirax (acyclovir)	Valtrex v. Zovirax	Valtrex

Notes. In a head-to-head comparison of excluded versus recommended drugs in the same class, 9 of 18 excluded drugs had better cost-per-QALY numbers. And 6 of the excluded drugs had cost-per-QALY numbers below \$50,000 per QALY.

not, however, correlate with exclusion or recommended status on PBM exclusion lists. The fact that exclusion lists vary significantly across the two PBMs analyzed, with one excluding products that the other recommends, suggests that in many instances, rebates rather than cost-effectiveness calculations play an important role. Further evidence of the importance of rebates can be



inferred from the fact that there were many cases of exclusion of a drug by one PBM but inclusion by the other. This indicates negotiations of a rebate between a drug manufacturer and the PBM recommending the drug. We also observed that in head-to-head comparisons of excluded versus recommended brand-name drugs, in about half the instances, the more cost-effective brand was given exclusion status by a PBM. A number of drugs, including notably the diabetes drug liraglutide (Victoza), have been excluded by one PBM despite having demonstrated superior cost-effectiveness (Nauck et al. 2009; Gough 2012).

Lack of evidence may play a role in determining a product's excluded status, as we could find no evidence for 23 excluded products, compared with no evidence for five recommended drugs. In theory, lack of evidence of cost-effectiveness adds to PBM or payer uncertainty regarding a drug's value, which in turn increases the likelihood that a drug will be excluded.

As we look to the future, more aggressive formulary management by PBMs, such as the use of exclusion lists, is expected to moderate the rate of prescription drug cost growth (Herper 2016). PBMs appear to be altering the pharmaceutical market dynamics by increasing competition among drug companies. The threat of exclusion alone will likely induce discounting on the part of drug companies wishing to better position themselves on PBM formularies. It is probable that PBMs and payers will continue to respond to rising drug costs by imposing an increasing number of restrictions on certain drugs. Indeed, we see that both CVS Caremark and Express Scripts have published provisional lists for 2017 showing increased numbers of excluded products. Other PBMs and payers have followed suit, and the proliferation of exclusion lists is expected to continue. In the near future, excluded products may include new generation lipid-lowering agents and oncology drugs (Shrank, Barlow, and Brennan 2015). In turn, this will challenge the biopharmaceutical industry to provide more concrete evidence of clinical superiority and cost-effectiveness of their products, particularly if excluded status becomes more value-based.

Rebates can combat drug cost inflation by lowering drug acquisition costs for the PBM, and these cost savings may be passed on to employer, payers, and end-users (patients). But it is not clear the precise extent to which cost savings are achieved or the amount that is passed on (Rentmeester and Garis 2008; Department of Health and Human Services 2011). Moreover, rebates have been criticized for not being based on cost-effectiveness (Chambers 2014). That is, the rebate negotiations do not appear to be related to value in

terms of health outcomes in relation to cost. Given the desire on the part of policy makers to move toward value-based payments in our health care system, a continuation of status quo rebating may not be desirable. More transparency on reasoning underlying rebating and allocation of cost savings would address policy maker concerns.

It should be noted that this study has several limitations. First, our study only included cost-per-QALY data. Less frequently used cost-effectiveness measures such as “cost per life year gained,” “cost per avoided hospitalization,” and “cost per target reached” were excluded. Second, we acknowledge that there are issues with both the validity and applicability of the QALY concept and use of cost-per-QALY estimates to inform pricing and reimbursement decisions. Furthermore, cost-effectiveness (e.g., cost-per-QALY) analyses may not be appropriate for PBMs that have a short-term horizon and are mostly focused on management of the pharmacy benefit. In addition, different cost-effectiveness studies have different estimation methodologies. Third, we did not examine the impact of exclusion lists on patient health outcomes. To do this, researchers would require utilization and outcomes data. Express Scripts predicted that in 2016, <0.5 percent of patients will be asked to switch to a different drug than the one they are currently using as a result of exclusion lists (Express Scripts, 2015). A half percent of 80 million members covered by Express Scripts is approximately 400,000 covered lives. Some of these 400,000 individuals will be asked to switch from an excluded to a recommended drug in spite of the fact that in some instances the excluded drug is clinically superior. Further research should be conducted to study the effect of exclusion lists on patients’ access to the best available treatments.

## CONCLUSIONS

From 2014 to 2016, the number of drugs on exclusion lists of the two largest PBMs in the United States grew by 65 percent. The mean cost-per-quality-adjusted life-year (QALY) for excluded drugs was higher (\$51,611) than the cost-per-QALY for recommended drugs (\$49,474). However, this was not statistically significant. Cost-effectiveness does not appear to correlate with a drug’s excluded or recommended status. On the other hand, lack of evidence appears to be a factor favoring a drug’s excluded status. Drug manufacturer rebates to PBMs appear to play an important role in determining exclusion and recommendation decisions.

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Additional supporting information may be found online in the supporting information tab for this article:

Appendix SA1: Author Matrix.

Appendix SA2: Supporting Information.